Sensipar (cinacalcet) Prior Authorization Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
2/1/2024	

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Sensipar® (cinacalcet) Tablets*	Treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis • Limitations of Use: ○ Not indicated for use in patients with CKD who are not on dialysis because of an increased risk of hypocalcemia. Treatment of hypercalcemia in adult patients with parathyroid carcinoma Treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy	*generic available	1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Secondary Hyperparathyroidism (HPT) in patients with Chronic Kidney Disease (CKD)	Secondary hyperparathyroidism (HPT) is a frequent complication in patients with chronic kidney disease (CKD). Declining kidney function results in decreased renal phosphate excretion, reduced synthesis of calcitriol (the active form of vitamin D), and decreased extracellular ionized calcium concentration. These derangements in mineral homeostasis promote continuous stimulation of the parathyroid glands and eventually parathyroid hyperplasia. The implications of secondary HPT include renal osteodystrophy, progressive vascular calcification, and in turn, cardiovascular disease and death.(3,4) Guidelines recommend that treatment options for HPT in dialysis patients include a combination of phosphate binders, vitamin D analogs, and calcimimetics. Parathyroidectomy is effective in suitable candidates refractory to medical therapy. Management of hyperphosphatemia involves dietary phosphate restriction and use of phosphate binders to block absorption of ingested phosphates. Phosphate binders are categorized as calcium-containing and non-calcium-containing. Calcium-containing binders include calcium carbonate and calcium acetate. Major non-calcium-containing binders include sevelamer and lanthanum. Synthetic vitamin D analogs (paricalcitol, doxercalciferol) and calcitriol increase the absorption of both calcium and phosphorus and reduce the synthesis of parathyroid hormone (PTH). Calcimimetics [Sensipar

	(cinacalcet), Parsabiv (etelcalcetide)] increase the sensitivity of the parathyroid calcium-sensing receptor (CaSR) to calcium. CaSR regulates the parathyroid gland hyperplasia and PTH secretion. Calcimimetics reduce the plasma PTH concentration and decrease calcium and phosphate levels.(2,3,4)
Parathyroid Carcinoma	Parathyroid carcinoma has been estimated to cause hyperparathyroidism (HPT) in approximately 1-2% of cases of primary HPT. Parathyroid carcinoma is suspected in patients presenting with marked hypercalcemia and serum PTH, as well as a palpable cervical mass. Surgery is the only effective therapy for parathyroid carcinoma. Medical management of patients with unresectable disease includes agents such as bisphosphonates and calcimimetics.(5,6)
Primary Hyperparathyroidism	Primary hyperparathyroidism (HPT) is a common disorder that arises from autonomous overproduction of parathyroid hormone (PTH) by abnormal parathyroid glands. It is characterized by the persistent elevation of total serum calcium levels with corresponding elevated or inappropriately normal PTH levels. Parathyroidectomy is the only definitive treatment of primary HPT. Symptomatic patients are expected to derive clear benefits from curative parathyroidectomy, and patients considered to be asymptomatic frequently report improvement in quality of life indexes.(7) For patients who decline or are not candidates for surgery, medical therapy such as calcimimetics should be considered.(8)
Safety (1)	Cinacalcet treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range.

REFERENCES

Number	Reference
1	Sensipar prescribing information. Amgen Inc. December 2019.
2	Kidney Disease Improving Global Outcomes (KDIGO) 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2017;7(1):1-59.
3	Cunningham J, Locatelli F, Rodriguez M. Secondary Hyperparathyroidism: Pathogenesis, Disease Progression, and Therapeutic Options. Clin J Am Soc Nephrol. 2011;6(4):913-921.
4	Cozzolino M, Galassi A, Conte F, et al. Treatment of Secondary Hyperparathyroidism: The Clinical Utility of Etelcalcetide. Ther Clin Risk Manag. 2017;13:679-689.
5	PDQ Adult Treatment Editorial Board. PDQ Parathyroid Cancer Treatment. Bethesda, MD: National Cancer Institute. Updated July 2020. Available at: https://www.cancer.gov/types/parathyroid/hp/parathyroid-treatment-pdq.
6	Long KL, Sippel RS. Current and Future Treatments for Parathyroid Carcinoma. Int J Endocr Oncol. 2018;5(1):1-10.
7	Wilhelm SM, Wang TS, Ruan DT, et al. The American Association of Endocrine Surgeons Guidelines for Definitive Management of Primary Hyperparathyroidism. JAMA Surg. 2016;151(10):959-968.
8	Marcocci C, Bollerslev J, Aziz-Khan A, Shoback DM. Medical Management of Primary Hyperparathyroidism: Proceedings of the Fourth International Workshop on the Management of Asymptomatic Primary Hyperparathyroidism. J Clin Endocrinol Metab. 2014;99(10):3607-3618.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Sensipar	cinacalcet hcl tab	30 MG ; 60 MG ; 90 MG	M ; N ; O ; Y	O ; Y		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Sensipar	cinacalcet hcl tab	30 MG ; 60 MG ; 90 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   - A. The patient has a diagnosis of hypercalcemia due to parathyroid carcinoma **OR**
   - B. The patient has a diagnosis of primary hyperparathyroidism (HPT) and BOTH of the following:
     1. The patient has a pretreatment serum calcium level that is above the testing laboratory's upper limit of normal **AND**
     2. The patient is unable to undergo parathyroidectomy **OR**
   - C. The patient has a diagnosis of secondary hyperparathyroidism (HPT) due to chronic kidney disease (CKD) AND ALL of the following:
     1. The patient is on dialysis **AND**
     2. The patient has a pretreatment or current intact PTH (iPTH) level that is >300 pg/mL **AND**
     3. ONE of the following:
        - A. The patient has tried and had an inadequate response to a phosphate binder [e.g., calcium acetate, calcium carbonate, Renvela (sevelamer carbonate), Fosrenol (lanthanum carbonate), Renagel (sevelamer hydrochloride)] **OR**
        - B. The patient has an intolerance or hypersensitivity to phosphate binder therapy **OR**
        - C. The patient has an FDA labeled contraindication to ALL phosphate binder agents **OR**
        - D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
          1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
          2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
          3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        - E. The prescriber has provided documentation that ALL phosphate binder agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
     4. ONE of the following:
        - A. The patient has tried and had an inadequate response to a vitamin D analog [e.g., calcitriol, Hectorol (doxecalciferol), Rayaldee (calcifediol), Zemplar (paricalcitol)] **OR**
        - B. The patient has an intolerance or hypersensitivity to vitamin D analog therapy **OR**
        - C. The patient has an FDA labeled contraindication to ALL vitamin D analog agents **OR**

Module	Clinical Criteria for Approval
	D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL vitamin D analog agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** D. The patient has another FDA approved indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another calcium sensing receptor agonist [e.g., Parsabiv (etelcalcetide)] **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior authorization process **AND** 2. ONE of the following: A. The patient has a diagnosis of hypercalcemia due to parathyroid carcinoma **OR** B. BOTH of the following: 1. The patient has a diagnosis of primary hyperparathyroidism (HPT) **AND** 2. The patient's serum calcium level has been evaluated to confirm the appropriateness of the current dose **OR** C. The patient has a diagnosis of secondary hyperparathyroidism (HPT) due to chronic kidney disease (CKD) AND BOTH of the following: 1. The patient is on dialysis **AND** 2. The patient's intact PTH (iPTH) level has been evaluated to confirm the appropriateness of the current dose **OR** D. The patient has another FDA approved indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another calcium sensing receptor agonist [e.g., Parsabiv (etelcalcetide)] **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months

